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SECTION 5

MAY 13 2011

510(K) SUMMARY — SPECIAL 510(k)

Submitter- Manufacturer: **Proxy Biomedical Ltd.,**
Denise Kennedy ,Quality Assurance Manager
Coilleach, Spiddal,
Galway, Ireland.
Tel: + 353 91 896900
30048-59928

Submitted by and Contact Person
Elaine Duncan
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082
715-549-6035
715-549-5380

CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: **April 14, 2011**

TRADE NAME: **VitaMesh™ Blue Lightweight Macroporous PP Surgical Mesh**
(and as also known by various other trade names)

COMMON NAME:	**Surgical Mesh**
CLASSIFICATION NAME:	**Surgical Mesh Polymeric**
REGULATION	21 CFR 878.3300
PROCODE and CLASS	General and Plastic Surgery, FTL: Class II

SUBSTANTIALLY EQUIVALENT TO: **VitaMesh™ Blue Lightweight Macroporous PP Mesh** is a modification of and is therefore substantially equivalent to VitaMesh™ surgical mesh, cleared under K060520. The addition of a colorant (blue) and modifications to the mesh physical properties do not introduce new risks nor do they affect the fundamental performance of the predicate product.

DESCRIPTION of the DEVICE: **VitaMesh™ Blue Lightweight Macroporous PP Surgical Mesh, a** modification of VitaMesh™ Surgical Mesh, is a non-absorbable, synthetic mesh, with a blue colorant to enhance visibility. The more open weave and reduced thickness provides a more drapeable and lighter texture.

INDICATIONS FOR USE: **VitaMesh™ Blue** Lightweight Macroporous PP Surgical Mesh is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing.

SUMMARY of TESTING: Design verification tests were per the requirements of 'Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh, March 2, 1999' and showed comparable properties to the VitaMesh.. Additional qualification testing included biocompatibility and animal implant comparative study which showed comparable safety performance and equivalent healing properties when compared to predicate product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Proxy Biomedical, Ltd.
% Paladin Medical, Inc.
Ms. Elaine Duncan
P.O. Box 560
Stillwater, Minnesota 55082

MAY 13 2011

Re: K111121
Trade/Device Name: VitaMesh™ Blue Lightweight Macroporous PP Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: April 14, 2011
Received: April 21, 2011

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111121

Device Name: **VitaMesh™ Blue Lightweight Macroporous PP Surgical Mesh**

Indications for Use:

VitaMesh™ Blue Lightweight Macroporous PP Surgical Mesh is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111121

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